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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	Miller.P001
First Inventor or Application Identifier	Jon M. Miller
Title	Substance to prevent or reverse weight gain induced by psychoactive agents
Express Mail Label No.	EL254093981US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231**

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* 15]
   (preferred arrangement set forth below)
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [1] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 1]
4. Oath or Declaration [*Total Pages* 2]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

** NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).*

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [ ] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. [ ] Other: .....

16. If a **CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*

[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____

Prior application information: Examiner _____ *Group / Art Unit:* _____

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17. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* *or* [X] *Correspondence address below*

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Signature		*Date*	03/29/99

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR

Docket Number (Optional): Miller.P001

Applicant, Patentee, or Identifier: Jon M. Miller

Application or Patent No.: _____

Filed or Issued: _____

Title: Substance to prevent or reverse weight gain induced by psychoactive agents

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- [X] the specification filed herewith with title as listed above.
- [ ] the application identified above.
- [ ] the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- [X] No such person, concern, or organization exists.
- [ ] Each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

Jon M. Miller		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
J. M. Miller		
Signature of inventor	Signature of inventor	Signature of inventor
25 MARCH 1999		
Date	Date	Date

UNITED STATES PATENT APPLICATION

for

A SUBSTANCE TO PREVENT OR REVERSE WEIGHT GAIN INDUCED BY PSYCHOACTIVE AGENTS

Inventor:

Jon M. Miller

Prepared by:

Matthew J. Cohen
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File No.:Miller.P001

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates to medications used for weight control. More particularly, the present invention relates to the use of a histamine H_2-receptor antagonist with antipsychotic and mood stabilizing drugs to control weight.

Description of the Prior Art:

Numerous innovations for substances to prevent or reverse weight gain have been provided in the past. Even though these innovations may be suitable for the specific individual purposes to which they address, they differ from the present invention because they fail to describe or claim at least one combination of the features depicted in the present invention. Even though these innovations may be suitable for the specific individual purposes to which they address, they would not be suitable for the purposes of the present invention as heretofore described.

SUMMARY OF THE INVENTION

The present invention prevents and reverses weight gain associated with the use of olanzapine and other antipsychotic drugs. The combination of psychoactive drugs and histamine H_2-receptor antagonists may represent a combined single dose delivery system or multiple drug regimen taken at preselected times. The psychoactive drugs are dosed as recommended by the manufacturer and the histamine H_2-receptor antagonists are dosed as for use in maintenance treatment of duodenal ulcer.

The types of problems encountered in the prior art are weight gain associated with the use of antipsychotic and mood stabilizing drugs, particularly olanzapine.

The problem was solved by the present invention because it was discovered that adding histamine H_2-receptor antagonists such as nizatidine or famotidine had a positive effect on weight gain associated with the use of antipsychotic and mood stabilizing drugs.

Accordingly, it is an object of the present invention to prevent or reduce weight gain in patients using antipsychotic and mood stabilizing medication.

In keeping with these objects, and with others which will become apparent hereinafter, one feature of the present invention resides, briefly stated, in the addition of histamine H_2-receptor antagonists to a regimen of psychoactive drugs such as the antipsychotic drugs, olanzapine, clozapine, risperidone, and quetiapine.

When the medication combination is designed in accordance with the present invention, weight gain is reduced or eliminated.

In accordance with another feature of the present invention, the addition of histamine H_2-receptor antagonists to a regimen of mood stabilizing drug such as divalproex sodium, valproic acid, and mirtazapine reduces or eliminates weight gain.

The novel features which are considered characteristic for the invention are set forth in the appended claims. The invention itself, however, both as to its construction and its method of operation, together with additional objects and advantages thereof, will be best understood from the following description of the specific embodiments when read and understood in connection with the accompanying drawings.

LIST OF REFERENCE NUMERALS

UTILIZED IN THE DRAWINGS

10 - substance to prevent or reverse weight gain (10)

12 - antipsychotic drug (12)

12A - olanzapine (12A)

12B - clozapine (12B)

12C - risperidone (12C)

12D - quetiapine (12D)

14 - mood stabilizing drug (14)

14A - divalproex sodium (14A)

14B - valproic acid (14B)

14C - mirtazapine (14C)

16 - histamine H2 - receptor antagonist (16)

16A - nizatidine (16A)

16B - famotidine (16B)

16C - cimetidine (16C)

16D - ranitidine (16D)

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a block diagram of a substance to prevent or reverse weight gain.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to **FIGURE 1** which is a block diagram of a substance to prevent or reverse weight gain. The substance to prevent or reverse weight gain (10) having an antipsychotic drug (12) or mood stabilizing drug (14) in a concentration from 0.01% to 99.99% in combination with a histamine H2 - receptor antagonist (16) in a concentration from 99.99% to 0.01%.

The antipsychotic drug (12) is selected from a group consisting of olanzapine (12A), clozapine (12B), risperidone (12C), and quetiapine (12D). The antipsychotic drug (12) is typically in a concentration of 10% to 90%, 30% to 60% and 50%.

The mood stabilizing drug (14) is selected from a group consisting of divalproex sodium (14A), valproic acid (14B), and mirtazapine (14C). The mood stabilizing drug (14) is typically in a concentration of 10% to 90%, 30% to 60% and 50%.

The histamine H2 - receptor antagonist (16) is selected from a group consisting of nizatidine (16A), famotidine (16B), cimetidine (16C) and ranitidine (16D). The histamine H2 - receptor antagonist (16) is in a concentration of 90% to 10%. The histamine H2 - receptor antagonist (16) is typically in a concentration of 60% to 30% and 50%.

The substance to prevent or reverse weight gain (10) is formulated in the following combinations;

10 parts of olanzapine (12A) are combined with 150 parts of nizatidine (16A) or ranitidine (16D)

10 parts of olanzapine (12A) are combined with 20 parts of famotidine (16B)

10 parts of olanzapine (12A) are combined with 400 parts of cimetidine (16C)

3 parts of risperidone (12C) are combined with 75 parts of nizatidine (16A) or ranitidine (16D)

3 parts of risperidone (12C) are combined with 10 parts of famotidine (16B)

3 parts of risperidone (12C) are combined with 200 parts of cimetidine (16C)

100 parts of quetiapine (12D) are combined with 50 parts of nizatidine (16A) or ranitidine (16D)

100 parts of quetiapine (12D) are combined with 7 parts of famotidine (16B)

100 parts of quetiapine (12D) are combined with 135 parts of cimetidine (16C)

30 parts of mirtazapine (14C) are combined with 150 parts of nizatidine (16A) or ranitidine (16D)

30 parts of mirtazapine (14C) are combined with 20 parts of famotidine (16B)

30 parts of mirtazapine (14C) are combined with 400 parts of cimetidine (16C)

250 parts of divalproex sodium (14A) are combined with 50 parts of nizatidine (16A) or ranitidine (16D)

250 parts of divalproex sodium (14A) are combined with 7 parts of famotidine (16B)

250 parts of divalproex sodium (14A) are combined with 135 parts of cimetidine (16C)

It will be understood that each of the elements described above, or two or more together, may also find a useful application in other types of constructions differing from the type described above.

While the invention has been illustrated and described as embodied in a Substance to Prevent or Reverse Weight Gain Induced by Psychoactive Agents, it is not intended to be limited to the details shown, since it will be understood that various omissions, modifications, substitutions and changes in the forms and details of the device illustrated and in its operation can be made by those skilled in the art without departing in any way from the spirit of the present invention.

Without further analysis, the foregoing will so fully reveal the gist of the present invention that others can, by applying current knowledge, readily adapt it for various applications without omitting features that, from the standpoint of prior art, fairly constitute essential characteristics of the generic or specific aspects of this invention.

What is claimed as new and desired to be protected by Letters Patent is set forth in the appended claims.

What Is Claimed Is:

1. A substance to prevent or reverse weight gain induced by psychoactive agents(10) comprising:

A) an antipsychotic drug (12) or mood stabilizing drug (14) in a concentration from 0.01% to 99.99%; and

B) a histamine H2 - receptor antagonist (16) in a concentration from 99.99% to 0.01%.

2. A substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 1, wherein the antipsychotic drug (12) is selected from a group consisting of olanzapine (12A), clozapine (12B), risperidone (12C), and quetiapine (12D).

3. A substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 1, wherein the mood stabilizing drug (14) is selected from a group consisting of divalproex sodium (14A), valproic acid (14B), and mirtazapine (14C).

4. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 1, wherein the histamine H2 - receptor antagonist (16) is selected from a group consisting of nizatidine (16A),famotidine (16B), cimetidine (16C) and ranitidine (16D).

5. The substance to prevent or reverse weight gain (10) as described in claim 2, wherein the antipsychotic drug (12) is in a concentration of 10% to 90%.

6. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 5, wherein the antipsychotic drug (12) is in a concentration of 30% to 60%.

7. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 6, wherein the antipsychotic drug (12) is in a concentration of 50%.

8. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 3, wherein the mood stabilizing drug (14) is in a concentration of 10% to 90%.

9. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 8, wherein the the mood stabilizing drug (14) is in a concentration of 30% to 60%.

10. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 9, wherein the mood stabilizing drug (14) is in a concentration of 50%.

11. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein the histamine H2 - receptor antagonist (16) is in a concentration of 90% to 10%.

12. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 11, wherein the histamine H2 - receptor antagonist (16) is in a concentration of 60% to 30%.

13. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 12, wherein the histamine H2 - receptor antagonist (16) is in a concentration of 50%.

13. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 10 parts of olanzapine (12A) are combined with 150 parts of nizatidine (16A) or ranitidine (16D).

14. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 10 parts of olanzapine (12A) are combined with 20 parts of famotidine (16B).

15. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 10 parts of olanzapine (12A) are combined with 400 parts of cimetidine (16C).

16. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 3 parts of risperidone (12C) are combined with 75 parts of nizatidine (16A) or ranitidine (16D).

17. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 3 parts of risperidone (12C) are combined with 10 parts of famotidine (16B).

18. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 3 parts of risperidone (12C) are combined with 200 parts of cimetidine (16C).

19. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 100 parts of quetiapine (12D) are combined with 50 parts of nizatidine (16A) or ranitidine (16D).

20. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 100 parts of quetiapine (12D) are combined with 7 parts of famotidine (16B).

21. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 100 parts of quetiapine (12D) are combined with 135 parts of cimetidine (16C).

22. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 30 parts of mirtazapine (14C) are combined with 150 parts of nizatidine (16A) or ranitidine (16D).

23. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 30 parts of mirtazapine (14C) are combined with 20 parts of famotidine (16B).

24. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 30 parts of mirtazapine (14C) are combined with 400 parts of cimetidine (16C).

25. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 250 parts of divalproex sodium (14A) are combined with 50 parts of nizatidine (16A) or ranitidine (16D).

26. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 250 parts of divalproex sodium (14A) are combined with 7 parts of famotidine (16B).

27. The substance to prevent or reverse weight gain induced by psychoactive agents (10) as described in claim 4, wherein 250 parts of divalproex sodium (14A) are combined with 135 parts of cimetidine (16C).

ABSTRACT OF THE DISCLOSURE

A substance to prevent or reverse weight gain induced by psychoactive agents (10) having an antipsychotic drug (12) or mood stabilizing drug (14) in a concentration from 0.01% to 99.99% in combination with a histamine H2 - receptor antagonist (16) in a concentration from 99.99% to 0.01%. The antipsychotic drug (12) is selected from a group consisting of olanzapine (12A), clozapine (12B), risperidone (12C), and quetiapine (12D). The antipsychotic drug (12) is typically in a concentration of 10% to 90%, 30% to 60% and 50%. The mood stabilizing drug (14) is selected from a group consisting of divalproex sodium (14A), valproic acid (14B), and mirtazapine (14C). The mood stabilizing drug (14) is typically in a concentration of 10% to 90%, 30% to 60% and 50%. The histamine H2 - receptor antagonist (16) is selected from a group consisting of nizatidine (16A), famotidine (16B), cimetidine (16C) and ranitidine (16D). The histamine H2 - receptor antagonist (16) is in a concentration of 90% to 10%. The histamine H2 - receptor antagonist (16) is typically in a concentration of 60% to 30% and 50%.

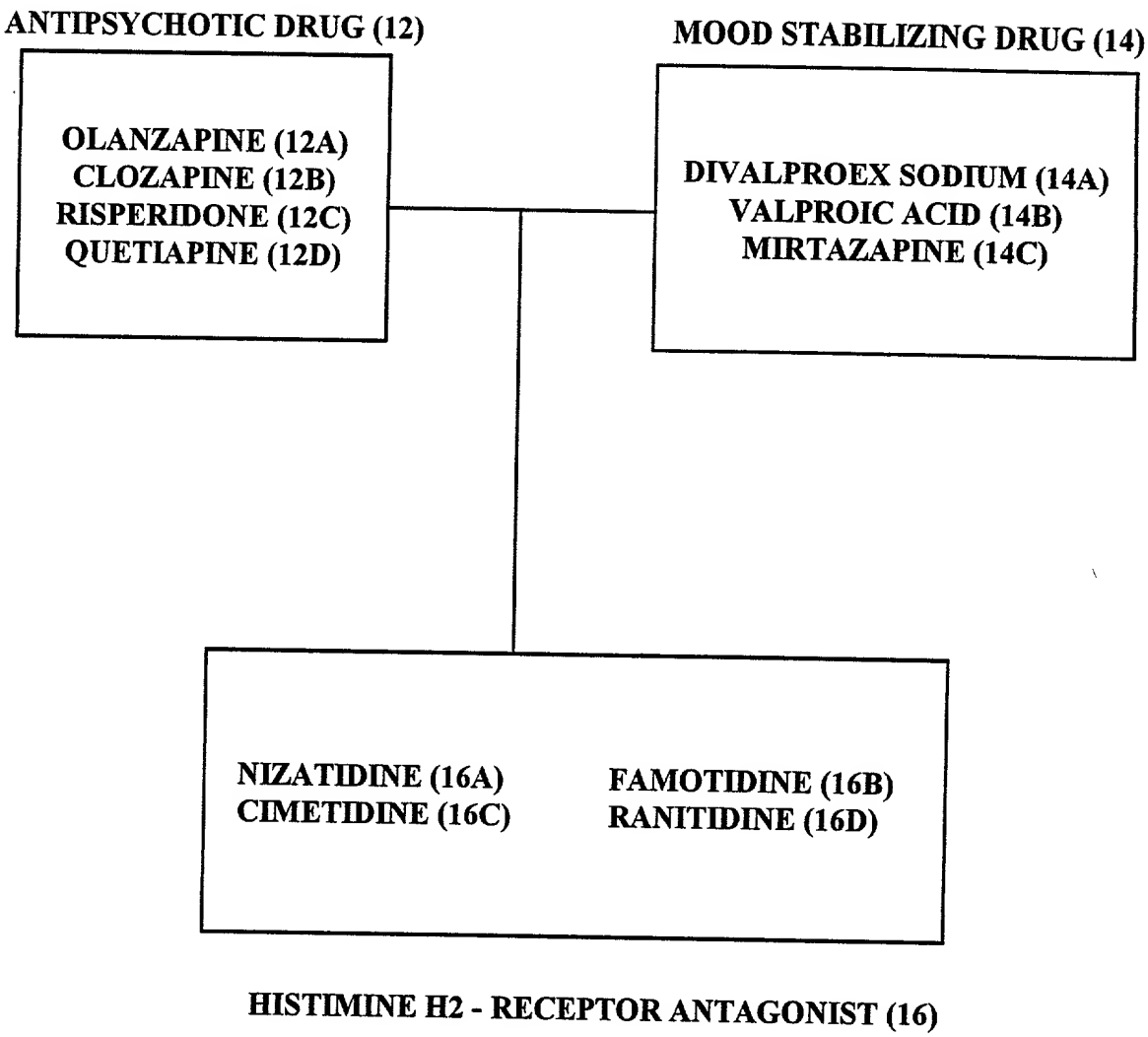
ANTIPSYCHOTIC DRUG (12)
OLANZAPINE (12A)
CLOZAPINE (12B)
RISPERIDONE (12C)
QUETIAPINE (12D)
MOOD STABILIZING DRUG (14)
DIVALPROEX SODIUM (14A)
VALPROIC ACID (14B)
MIRTAZAPINE (14C)
NIZATIDINE (16A)
CIMETIDINE (16C)
FAMOTIDINE (16B)
RANITIDINE (16D)
HISTIMINE H2 - RECEPTOR ANTAGONIST (16)

FIG. 1

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	Miller.P001
First Named Inventor	Jon M. Miller
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Substance to prevent or reverse weight gain induced by psychoactive agents

(Title of the Invention)

the specification of which
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*
OR
☒ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Matthew J. Cohen	42,426		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Jon M.	Miller

Inventor's Signature	Jon M. Miller					Date	3/25/99
Residence: City	Louisville	State	KY	Country	40242	Citizenship	USA
Post Office Address	8501 Rhett Butler Dr.						
Post Office Address							
City	Louisville	State	KY	ZIP	40242	Country	USA

☐ Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto